Notice of Allowability	Application No.	Applicant(s)	
	09/194,164	DAN ET AL.	
	Examiner	Art Unit	
	Christopher H. Yaen	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *11/23/2004*.

2. ☒ The allowed claim(s) is/are *86,87,90,95-99,101,103-112,115-123,125-130 and 132-147*.

3. ☒ The drawings filed on *20 November 1998* are accepted by the Examiner.

4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
      1. ☒ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 5/14/99 & 11/23/04
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
5/13/05

Christopher Yaen
Art Unit 1642

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Debra Glaister on 5/13/2005.

The application has been amended as follows:

Claims 1-85 (Canceled)

Claim 86 (Currently amended): An isolated polynucleotide comprising a sequence that encodes an antigen binding polypeptide wherein the polypeptide comprises an H chain V region [[or]] and an L chain V region of the polypeptide encoded by the nucleic acid sequence as shown in SEQ ID NO:13, and wherein the antigen binding polypeptide specifically recognizes a cancer cell surface antigen and does not recognize a normal non-cancerous cell surface antigen.

Claim 87 (Previously presented): The polynucleotide of claim 86, wherein said antigen binding polypeptide specifically recognizes any one or more of at least glioma, melanoma, breast carcinoma, lung carcinoma, ovarian carcinoma, lymphoma, gastric carcinoma, colon carcinoma or prostate carcinoma cells.

Claims 88-89 (Canceled)

Claim 90 (Currently amended): The polynucleotide of claim 86, wherein the polynucleotide encodes ~~either or~~ both of the amino acid sequences of the H chain V region and the L chain V region of the polypeptide as shown in SEQ ID N0:14.

Claims 91-94 (Canceled)

Claim 95 (Previously presented): The polynucleotide of claim 86 or 87, wherein the antigen binding polypeptide comprises a CDR region of the polypeptide as shown in SEQ ID NO:14.

Claim 96 (Previously presented): The polynucleotide of claim 86 or 87, wherein the antigen binding polypeptide comprises at least one of the H chain CDR1, CDR2, or CDR3 of the polypeptide as shown in SEQ ID NO:14.

Claim 97 (Previously presented): The polynucleotide of claim 96, wherein the antigen binding polypeptide comprises the H chain CDR2 of the polypeptide as shown in SEQ ID NO:14.

Claim 98 (Previously presented): The polynucleotide of claim 96, wherein the antigen binding polypeptide comprises the H chain CDR3 of the polypeptide as shown in SEQ ID NO:14.

Claim 99 (Previously presented): The polynucleotide of claim 96, wherein the antigen binding polypeptide comprises the H chain CDR2 and CDR3 of the polypeptide as shown in SEQ ID NO:14.

Claim 100 (Canceled)

Claim 101 (Previously presented): The polynucleotide of claim 86 or 87, wherein the antigen binding polypeptide comprises the L chain CDR3 of the polypeptide as shown in SEQ ID NO:14.

Claim 102 (Canceled)

Claim 103 (Currently amended): The polynucleotide of claim 86 or 87, comprising the polynucleotide ~~as shown in~~ of SEQ ID NO:13.

Claim 104 (Previously presented): The polynucleotide of claim 86 or 87, wherein the antigen binding polypeptide comprises a variable region of the polypeptide as shown in SEQ ID NO:14.

Claim 105 (Previously presented): The polynucleotide of claim 86 or 87, wherein the polynucleotide further encodes at least one functional moiety.

Claim 106 (Previously presented): The polynucleotide of claim 105, wherein the at least one functional moiety is selected from the group consisting of a signal peptide, an agent that enhances immunologic reactivity, an agent that facilitate coupling to a solid support, a carrier, a bioresponse modifier, a toxin, a detectable label, and a drug.

Claim 107 (Previously presented): The polynucleotide of claim 106, wherein the signal peptide is prokaryotic.

Claim 108 (Previously presented): The polynucleotide of claim 106, wherein the agent that enhances immunologic reactivity is a bacterial superantigen.

Claim 109 (Previously presented): The polynucleotide of claim 106, wherein the bioresponse modifier is a cytokine.

Claim 110 (Previously presented): The polynucleotide of claim 106, wherein the chemically functional moiety is a toxin selected from the group consisting of ricin, pokeweed antiviral protein, Pseudomonas exotoxin A, diphtheria toxin, ricin A chain, restrictocin, and phospholipase enzymes.

Claim 111 (Previously presented): The polynucleotide of claim 86 or 87, wherein the antigen binding polypeptide is selected from the group consisting of whole native antibodies, bispecific antibodies, chimeric antibodies, Fab, F(ab')2, single chain V region fragments (scFv) and fusion polypeptides.

Claim 112 (Previously presented): The polynucleotide of claim 86 or 87, wherein said antigen binding polypeptide is an antigen binding polypeptide of a human antibody.

Claim3 113-114 (Canceled)

Claim 115 (Currently amended): [[A]] An isolated cloning vector comprising a polynucleotide of claim 86 or 87.

Claim 116 (Previously presented): An expression vector comprising a polynucleotide of claim 86 or 87.

Claim 117 (Currently amended): [[A]] An isolated host cell comprising a polynucleotide of claim 86 or 87.

Claim 118 (Previously presented): A composition comprising a polynucleotide of claim 86 or 87.

Claim 119 (Currently amended): A ~~process~~ method for making a polynucleotide of claim 86 or 87 comprising preparing the polynucleotide using one or method selected from: chemical synthesis, nucleic acid amplification, and recombinant cloning methods.

Claim 120 (Currently amended): A ~~process~~ method for making an antigen binding polypeptide by expressing a polynucleotide of claim 86 in a host cell.

Claim 121 (Currently amended): [[A]] An isolated polynucleotide encoding a

diabody comprising an antigen binding polypeptide according to claim 86 or 87.

Claim 122 (Currently amended): [[A]] An isolated polynucleotide encoding a dimer comprising an antigen binding polypeptide according to claim 86 or 87.

Claim 123 (Previously presented): The polynucleotide according to claim 86 or 87 wherein the antigen binding polypeptide does not specifically recognize any one of normal non-cancerous adrenal, bladder, cervix, esophagus, eye, heart, kidney, liver, muscle, pancreas, parotid, pituitary, small intestine, spinal cord, spleen, thymus, thyroid, testis, or uterus cells.

Claim 124 (Canceled)

Claim 125 (Previously presented): The polynucleotide of claim 86 or 87, wherein the antigen binding polypeptide is a humanized antigen binding polypeptide.

Claim 126 (Previously presented): The polynucleotide of claim 86 or 87, wherein the antigen binding polypeptide comprises a heterologous immunoglobulin constant region.

Claim 127 (Previously presented): The polynucleotide of claim 86 or 87, wherein the polynucleotide encodes a ScFv or antibody to a cancer cell surface epitope, wherein the ScFv or antibody is comprised of the amino acid sequences of the H chain V region and the L chain V region of the polypeptide as shown in SEQ ID NO:14, and wherein the antigen binding polypeptide specifically recognizes a cancer cell surface antigen and does not recognize a normal non-cancerous cell surface antigen.

Claim 128 (Previously presented): The polynucleotide of claim 86 or 87, wherein the antigen binding polypeptide is a polypeptide derivative or a functionally equivalent fragment of the ScFv or antibody.

Claim 129 (Currently amended): The polynucleotide of claim 86 or 87, wherein said antigen binding polypeptide comprises a H [[or]] and L chain CDR1, CDR2, or CDR3 which consists of the amino acid sequence of the corresponding CDR of said scFv or antibody or with exception of one or more deletions, additions or substitutions relative to the amino acid sequence, while having substantially the same specificity of the scFv or antibody.

Claim 130 (Previously presented): The polynucleotide of claim 86 or 87, wherein the antigen binding polypeptide comprises at least a portion of a variable region of [[the]] a scFv or antibody as shown in SEQ ID NO:14 such that said antigen binding polypeptide retains the specificity of the scFv or antibody.

Claim 131 (Canceled)

Claim 132 (Previously presented): The polynucleotide of claim 86 or 87, wherein the antigen binding polypeptide comprises an amino acid sequence for at least one CDR which plays a role in the specificity of the antibody as shown in SEQ ID NO:14.

Claim 133 (Canceled)

Claim 134 (Previously presented): An isolated polynucleotide comprising a sequence that encodes an antigen binding polypeptide, wherein said polypeptide comprises an H chain CDR3 that is encoded by the nucleic acid sequence as shown in SEQ ID NO:13, and wherein the antigen binding polypeptide specifically recognizes a cancer cell surface antigen and does not recognize a normal non-cancerous cell surface antigen.

Claim 135 (Previously presented): An isolated polynucleotide comprising a sequence that encodes an antigen binding polypeptide, wherein said polypeptide

comprises an L chain CDR3 that is encoded by the nucleic acid sequence as shown in SEQ ID NO:13, and wherein the antigen binding polypeptide specifically recognizes a cancer cell surface antigen and does not recognize a normal non-cancerous cell surface antigen.

Claim 136 (Previously presented): The isolated polynucleotide of claim 134 or 135, wherein said antigen binding polypeptide specifically recognizes any one or more of at least glioma, melanoma, breast carcinoma, lung carcinoma, ovarian carcinoma, lymphoma, gastric carcinoma, colon carcinoma or prostate carcinoma cells.

Claim 137 (Previously presented): The isolated polynucleotide of claim 134 or 135, wherein said antigen binding polypeptide is selected from the group consisting of whole native antibodies, bispecific antibodies, chimeric antibodies, Fab, F(ab')2, single chain V region fragments (scFv) and fusion polypeptides.

Claim 138 (Previously presented): The isolated polynucleotide of claim 134 or 135, wherein the polynucleotide further encodes at least one functional moiety.

Claim 139 (Previously presented): The isolated polynucleotide of claim 138, wherein the at least one functional moiety is selected from the group consisting of a signal peptide, an agent that enhances immunologic reactivity, an agent that facilitates coupling to a solid support, a carrier, a bioresponse modifier, a toxin, a detectable label, and a drug.

Claim 140 (Previously presented): The isolated polynucleotide of claim 139, wherein the signal peptide is prokaryotic.

Claim 141 (Previously presented): The isolated polynucleotide of claim 139, wherein the agent that enhances immunologic reactivity is a bacterial superantigen.

Claim 142 (Previously presented): The isolated polynucleotide of claim 139, wherein the bioresponse modifier is a cytokine.

Claim 143 (Previously presented): The polynucleotide of claim 138, wherein the functional moiety is a toxin selected from the group consisting of ricin, pokeweed antiviral protein, Pseudomonas exotoxin A, diphtheria toxin, ricin A chain, restrictocin, and phospholipase enzymes.

Claim 144 (Currently amended): [[A]] An isolated vector comprising a polynucleotide of claim 86, 103, 134 or 135.

Claim 145 (Currently amended): [[A]] An isolated host cell comprising a polynucleotide of claim 103, 134 or 135.

Claim 146 (Previously presented): A composition comprising a polynucleotide of claim 103, 134 or 135.

Claim 147 (New): An isolated polynucleotide comprising a sequence that encodes a polypeptide comprising an H chain V region or an L chain V region of the polypeptide encoded by the nucleic acid sequence as shown in SEQ ID NO:13.

All rejections and or objections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in the paper filed 11/23/2004

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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May 13, 2005

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5/12/05